Medical Device
EU Declaration of Conformity

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Annex IV of Medical Device Regulation (EU) 2017/745

The EU Declaration of Conformity is issued under the sole responsibility of CMC Hygea Ltd.

MDR Classification Rule	**Class 1 Medical Device under Rule 1**
Product Supplier	**CMC Hygea Ltd.**
Supplier Address	**Unit 630G, Northern Extension, IDA Industrial Park, Cleaboy Road, Waterford, Ireland X91HY58**

Product Code	**Basic UDI-DI**	**Product Trade Name & Description**
CMCU10001A	**539152805009CU**	**PathAguard LUCA (760mm x 250mm)**
CMCLL10001A	**539152805005CL**	**PathAguard LUCA Liner (660mm x 590mm)**
CMCU10002A	**539152805008CS**	**PathAguard LUCA Large (760mmx340mm)**
CMCD10002A	**539152805004CJ**	**PathAguard LUCA Dispenser**
CMCLLV10001A	**539152805010CD**	**PathAguard LUCA Liner Vessel**
CMCVC10001A	**539152805011CF**	**PathAguard LUCA Liner Vessel Carrier**
Intended Purpose	**PathAguard LUCA System is intended to aid the cleaning and treating of Lower Limb Ulcers and Wounds whilst inhibiting the opportunity for cross contamination by reducing the opportunity for pathogens to grow.**	

CMC Hygea Limited declares that device(s) listed above conforms to the relevant provisions of the Medical Device Regulation (EU) 2017/745 dated 5th April 2017 and is in accordance with Annex IV, as implemented by the European Union's Medical Devices Regulations.

Person Responsible Signature: **Michael Malone** **Chief Executive Officer** **CMC Hygea Ltd.** **Unit 630G, Northern Extension,** **IDA Industrial Park,** **Cleaboy Road,** **Waterford,** **Ireland** **X91HY58**	
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